REMARKS

The Examiner provides a number of rejections and we list them here in the order in which they are addressed:

I. Rejections Under 35 U.S.C § 112 ¶ 2.

A. Claims 1, 13, and 15-16 are rejected for allegedly not reciting an essential step.

B. Claims 17-34 are rejected for allegedly not reciting an essential step.

II. Rejections Under 35 U.S.C. § 103(a).

A. Claims 1, 13 and 15-16 are rejected for allegedly being obvious over Benning ("Biosynthesis and Function of the Sulfolipid Sulfoquinovosyl Diacylglycerol, "*Annu. Rev. Plant Physiol. Plant Mol. Biol.*, 49:53-75 (1998)) in view of Essignmann et al. and Guler et al.

B. Claims 17-25 are rejected for allegedly being obvious over Benning in view of Essigmann et al. and Guler et al. in further view of Stratagene Catalog, Hall et al. and Howard et al.

C. Claims 26-34 are rejected for allegedly being obvious over Benning in view of Essigmann et al. and Bevan et al. in further view of Stratagene Catalog, Hall et al. and Howard et al.

I. Claims 1, 13, 15-16 and 17-34 Do Not Lack An Essential Step

The Examiner states that Claims 1, 13, 15-16 and Claims 17-34 are "... incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: steps in isolating the final product is ... missing." *Office Action, pg. 7 and pg. 2.* The Applicant disagrees. The MPEP section cited by the Examiner is as follows:

> 2172.01 Unclaimed Essential Matter
> A claim which omits matter disclosed to be essential to the invention **as described in the specification or in other statements of record** may be rejected under 35 U.S.C. 112, first paragraph, as not enabling. In re Mayhew, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). See also MPEP § 2164.08(c). Such essential matter may include missing elements, steps or necessary structural cooperative relationships of elements **described by the applicant(s) as necessary** to practice the invention. [*emphasis added*]

The Examiner is requested to note that the MPEP indicates the "essential steps" question is triggered when the Applicants indicate in the specification that something is "essential." The Examiner points to nothing in the present specification to support the rejection.

The Federal Circuit has recently further explained that the holding of *In re Mayhew* is limited to cases where the invention is inoperable without a particular claimed step:

> ... *In re Mayhew*, 527 F.2d 1229, 1233, 188 USPQ 356, 358 (C.C.P.A. 1976), [is cited] for the proposition that "claims failing to recite a necessary element of the invention fail for lack of an enabling disclosure." **There, however, the method claims omitted a step without which the invention as claimed was wholly inoperative** (meaning it simply would not work and could not produce the claimed product). *Id.* ... Thus, the lack of a description of (or a limitation directed to) the expression vector itself (as separate from the EPO DNA and transcription control sequences) does not render the invention inoperable and therefore does not run afoul of *In re Mayhew*, 527 F.2d at 1233, 188 USPQ at 358 (affirming examiner's rejection of claims not limited to having a cooling zone at the exit of a steel strip from a zinc bath because the specification indicated that without that cooling bath the invented process would not work). *Amgen, Inc. v. Hoescht Marion Roussel*, Inc., 314 F.3d 1313, 1338, 65 U.S.P.Q.2D (BNA) 1385 (Fed. Cir, 2003).

The Applicants provide no teaching in the specification that in the absence of isolating the final product an inoperable invention will result and the Examiner has not presented any evidence to the contrary. The Applicants, therefore, respectively request the Examiner withdraw these rejections.

In any event, without acquiescing to the Examiner, but to further the prosecution, Applicants have added dependent claims directed to isolating the products.

II. The Claims Are Not Obvious

The Examiner has provided numerous references in various combinations in an effort to establish that the pending claims are obvious. The patentability of, on the one hand, Claims 17-34 and, on the other hand, Claims 1, 13 and 15-16, is argued separately below.

A. Claims 17-34 Are Patentable

The Applicants wish to remind the Examiner that, while not determinative, an excessive number of cited references (Claims 17-34 are rejection in two rejections with a combination of six and seven references, respectively) is viewed by the Federal Circuit as an

indicator of non-obviousness. In addition, Applicants feel compelled to point out:

1. The Examiner admits that the primary reference, Benning, "does not teach a method of producing UDP-SQ from UDP-glucose with the polypeptide encoded by SEQ ID NO:6." (Office Action, p. 3).

2. The Examiner points to nothing in Benning about the expression of *both* genes in a host cell.

3. The Examiner cites Hall et al. and Howard et al. merely for teaching "host cells" - nothing more.

4. Essigmann is cited merely for the SQD1 gene; again, the Examiner points to nothing in about the expression of *both* genes in a host cell.

5. The Examiner admits that Essigmann teaches that the sulfur donor is unknown; the Examiner apparently (incorrectly) considers it sufficient under patent law that "sulfite is a *plausible* sulfur donor." (Office Action, p. 4, emphasis added).

6. The Examiner cites to catalogs (Stratagene) merely for "vectors and host cells *capable* of undergoing multiple transformations." (Office Action, p. 4, emphasis added).

7. The Examiner argues there is motivation to combine because of "*possibly* increasing efficiency in production . . ." (Office Action, p. 4, emphasis added

Applicants submit that the above arguments collectively demonstrate that the Examiner a) is personally providing an argument of "desirability" and b) has established nothing other than the introduction of both genes into a single host cell might be - in light of the present specification - something to "try." With respect to the element of desirability, it is not for the Examiner to provide this element. The Federal Circuit has noted that: "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992). With respect to the Examiner's arguments about what is "possible," the Federal Circuit has made it clear that the argument that something is "obvious to try" is a discredited and impermissible standard. *American Hospital Supply Corp. v. Travenol Laboratories, Inc.*, 745 F.2d 1, 223 USPQ 577 (Fed. Cir. 1984) ("Of course, an 'obvious to try' standard is not a legitimate test of patentability.")

It is respectfully submitted that the Examiner's combination of references is really a house of cards. There is nothing specific in the entire collection of references which teaches

the presently claimed embodiment of the invention. Arguing that "transfecting a host cell with a desired gene is well known" adds nothing to the analysis. The question is whether the art teaches transfection with the *two particular genes* set forth in the claims. The Examiner's argument is equivalent to citing the Maniatis treatise as prior art. The Examiner is requested to take note of the various published decisions by the Board and Federal Circuit which point out that general protocols in treatises and catalogs are of no moment when the claims specify particular genes. The Examiner is requested to reconsider the rejections (perhaps with the Examiner's supervisor) in light of the above.

B. Claims 1, 13 and 15-16 Are Patentable

Claims 1, 13 and 15-16 also specify particular genes - not a generic method. Thus, the Examiner's statement that "co-expression of multiple proteins via multiple vectors are [sic] well known" (Office Action, p. 7) adds nothing to the analysis. The Examiner's burden is to provide a reference which teaches or suggests the combination of elements within the present claims. An unsupported statement about general protocols in the prior art is no substitute and does not satisfy the Examiner's burden.

Claim 1 also specifies the use of *both particular genes* in a method that is drafted broadly to include *in vitro* reactions. As a result, many of the Applicants' arguments made above apply. None of the cited references teach the use of *both* genes in the manner claimed. The Examiner is (improperly) adding elements that are NOT to be found in the cited references. As a result, the rejections are not supportable.

CONCLUSION

The Applicant believes that the arguments and claim amendments set forth above traverse the Examiner's rejections and, therefore, request that all grounds for rejection be withdrawn for the reasons set above. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Applicant encourages the Examiner to

call the undersigned collect at 617.252.3353.

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